

JUL 22 2008

**510(k) Summary for the PULSAR™ Generator
and PEAK PlasmaBlade™ Tissue Dissection Device**

1. Submitter name and address:

PEAK Surgical, Inc.
2464 Embarcadero Way
Palo Alto, CA 94303
Phone: 650-331-3022
Fax: 650-331-3293

Contact: Grace Carlson, MD

Date Prepared: October 29, 2007

2. Device Name:

Trade Name: PULSAR™ Generator and
PEAK PlasmaBlade™ Tissue Dissection Device
Common Name: Electrosurgical Device and Accessories
Classification Name: Electrosurgical Cutting and Coagulation Device and
Accessories (21 CFR 878.4400)

3. Predicate Devices:

Medtrex OR Pro 300 Electrosurgical Generator (K981724)
Ellman Surgitron 120 IEC (K013255)
Valleylab E2515 Electrosurgical Accessory (K791639)
Valleylab Coated Electrode (K962044)
Utah Medical Ceramic Blade Electrode (K960255)

4. Device description:

The PULSAR Generator is a microcontroller based, isolated output, electrosurgical unit that has been designed to produce monopolar and bipolar RF energy for cutting and coagulation during surgery. The PULSAR Generator is used with the PEAK PlasmaBlade Tissue Dissection Device, which is a single use, sterile handpiece for monopolar energy delivery. The PEAK PlasmaBlade Tissue Dissection Device consists of an insulated blade electrode, rotating bendable shaft, handle with integrated controls, and a cable. An optional footswitch may be used to operate the system in lieu of the controls on the PlasmaBlade handpiece.

5. Intended Use:

The PULSAR Electrosurgical Generator with the PlasmaBlade Tissue Dissection Device is intended to be used for cutting and coagulation of soft tissue during surgical procedures.

6. Technological Characteristics

The PULSAR Generator with the PEAK PlasmaBlade Tissue Dissection Device is similar to the predicate devices in that they are all electrosurgical instruments used to cut tissue and coagulate soft tissue, utilizing RF powered distal ends.

7. Performance Data

Preclinical laboratory and performance tests were executed to ensure the devices functioned as intended and met design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate devices, and meets safety and effectiveness criteria.

8. Sterilization

The PEAK PlasmaBlade Tissue Dissection Device is provided sterile. The device is not intended for reuse or resterilization.

9. Conclusions

By virtue of design, materials, function, and intended use, the PULSAR Generator and PEAK PlasmaBlade Tissue Dissection Device is substantially equivalent to FDA-cleared devices currently marketed in the United States. In establishing substantial equivalence to the predicate devices, PEAK Surgical evaluated the indications for use, materials incorporated, product specification and energy requirements of those systems.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2008

PEAK Surgical, Inc.
% Grace A. Carlson, MD
2464 Embarcadero Way
Palo Alto, California 94303

Re: K073057

Trade/Device Name: PULSAR™ Generator and PEAK PlasmaBlade™ Tissue Dissection
Device

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: II

Product Code: GEI

Dated: June 20, 2008

Received: June 23, 2008

Dear Dr. Carlson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: PULSAR™ Generator and
PEAK PlasmaBlade™ Tissue Dissection Device

Indications for Use:

The PULSAR Generator with the PEAK PlasmaBlade Tissue Dissection Device is intended to be used for cutting and coagulation of soft tissue during surgical procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

PEAK Surgical, Inc.
PULSAR Generator and PEAK PlasmaBlade Preformed
October 29, 2007

510(k) Number _____